

Q2 2021 Results

Play to Win

July 29, 2021



Forward looking statements

This document contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.



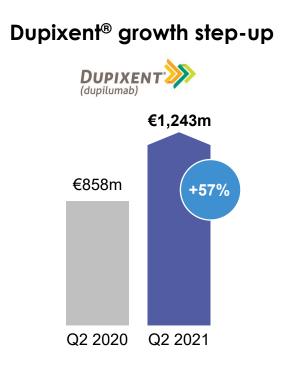
Agenda

Corporate update	Paul Hudson	Chief Executive Officer
	Bill Sibold	Specialty Care
Durain a an um alarka	Thomas Triomphe	Vaccines
Business update	Olivier Charmeil	General Medicines
	Julie Van Ongevalle	Consumer Healthcare
R&D update	John Reed	Global Head of R&D
Financial results	Jean-Baptiste de Chatillon	Chief Financial Officer
Q&A session		

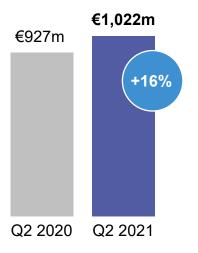


Accelerated sales and business EPS growth in Q2 2021





Vaccines up double-digit



Full-year 2021 business EPS guidance raised



Leaders with world-class pharma expertise strengthening the Executive Committee and EUROAPI Board



Brendan O'Callaghan, Executive Vice President, Global Head of Industrial Affairs⁽²⁾

- Joined Sanofi in 2015, Global Head for Biologics since 2016
- Prior roles at Merck & Co, Schering-Plough



Roy Papatheodorou, General Counsel and Head of Legal, Ethics and Business Integrity⁽³⁾

- General Counsel of Novartis Pharmaceuticals since 2017
- Prior roles at Actavis and Linklaters



Viviane Monges, Independent non-executive Chair of the Supervisory Board, EUROAPI(1)

- 30 years of Finance experience across different industries and geographies
- CFO roles at Nestlé, Galderma, Novartis, Wyeth Pharmaceuticals



- (1) effective July 1, 2021
- (2) effective October 1, 2021
- (3) effective February 1, 2022

Major progress on potentially transformative therapies

Priority Assets	Key accomplishments since CMD in Dec 2019	Submission ⁽¹⁾
Dupixent®(2)	6 pivotal trials started in additional indications ⁽³⁾ to realize fully the potential of this transformative medicine	2021+e
Amcenestrant	Potential best-in-class safety and efficacy profile to become endocrine backbone across all lines of ER+ breast cancer	2022e
Nirsevimab ⁽⁴⁾	Positive pivotal data demonstrated potential in all infant protection against RSV; filings to begin 1-year ahead of plan	2022e
Efanesoctocog alfa ⁽⁵⁾ & Fitusiran	Progressed pivotal programs to potentially bring efficacy and convenience of treatments for hemophilia patients to a new level	2022e
Tolebrutinib	Enrolling four Phase 3 trials across full spectrum of MS with >95% of patients retained on Phase 2b OLE ⁽⁶⁾	2024e



Making Sanofi more representative of society



Senior leadership positions held by women

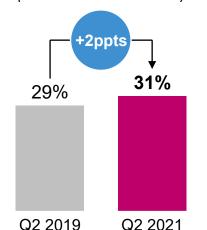
(2025 ambition: ~50%)





People of Color representation at Sanofi U.S.

(2025 ambition: ~37%)













LGBTQIA+ community inclusion in our workplace

- Ambassador program: recruiting 'safe points of contact' at French sites
- Rainbow flag flown:
 'Welcome Here' project in Australia
- Employee forum: raise awareness on discrimination in German workplace
- Employee digital workshop: on support tactics reached 500+ in Mexico
- Employee roundtables: with activists attended by 800+ in Brazil

On track to achieve our 'Play to Win' 2025 people ambitions

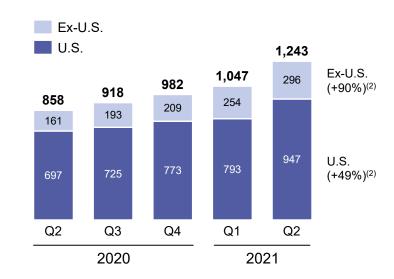


Dupixent® – annualizing at €5bn

- Accelerated performance in Q2
 - Worldwide growth of +57% vs. Q2 2020
 - Added nearly €200m in sales vs. Q1 2021
- In-office patient visits still below pre-COVID levels
 - U.S. patient visits remained at 80%⁽¹⁾ of pre-COVID levels
- Upcoming H2 milestones for potential future growth
 - FDA PDUFA for 6 to 11-year-olds with asthma (Oct 21st)
 - Pivotal data in patients <6 years with AD
 - Pivotal readouts in PN and EoE (Part B)

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Global Dupixent® quarterly sales (€m)



Well on track to achieve >€10bn peak sales target



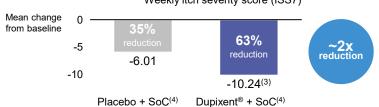


Dupixent® achieved positive Phase 3 results in CSU

- Chronic spontaneous urticaria (CSU) is a debilitating Type 2 inflammatory disease
 - Intense itch and hives significantly impacting QoL
 - Disease remains uncontrolled in 50% of patients on SoC
 - ~300k patients in the U.S. are biologics eligible⁽¹⁾
- Dupixent® met primary endpoints in Ph3 Study A⁽²⁾
 - Significant reduction in itch and urticaria activity (itch and hives) vs. baseline at week 24
- Data supports well-established safety profile
- Study B⁽²⁾ in omalizumab non-responders ongoing
 - Global regulatory submissions to begin in 2022

Dupixent® significantly reduced itch and urticaria activity in patients with CSU

Primary endpoint: Reduction in itch at week 24 Weekly itch severity score (ISS7)



Primary endpoint: Reduction in itch & hives at week 24 Weekly urticaria activity score (UAS7)





QoL: quality of life: SoC: standard of care

⁽¹⁾ moderate to severe CSU patients uncontrolled on antihistamines and other standard of care, excluding biologics; (2) LIBERTY CUPID clinical program; (3) p<0.001;

Dupixent® – large Type 2 population still to be unlocked





Atopic Dermatitis	Asthma & CRSwNP	Adjacent Type 2 indications(6,7)
 First and only biologic addressing younger population ages 6+ Favorable safety profile⁽¹⁾ ~2.2 million AD biologic eligible patients for ages 6+ 6.3% AD biologic eligible patient penetration⁽²⁾ <6yo potential ~75k opportunity 	 Best-in-class asthma Type 2 profile⁽³⁾ approved for ages 12+ ~900k biologic eligible 12+ 18% Asthma biologic penetration⁽⁴⁾; 24% Dupixent® NBRx share for Q2⁽⁵⁾ 6-11yo potential ~75k opportunity ~90K biologic eligible CRSwNP patients 	2021e Prurigo Nodularis 74k 2022e CSU 308k 2022e CindU-Cold 25k 2022e Eosinophilic esophagitis 48k 2023e Bullous Pemphigoid 27k 2023e Type 2 COPD 300k 2023e CRSsNP 130k 2024e+ AFRS 11k
>3m patient	s ⁽⁸⁾ addressable	Incremental >600k patients ⁽⁹⁾



Source: Sanofi Epidemiology Data primarily from Sanofi Real World Evidence platform; AD: moderate to severe atopic dermatitis; CRSwNP: chronic sinusitis with nasal polyposis; CSU: chronic spontaneous urticaria; CindU-Cold: chronic inducible urticaria-cold; COPD: chronic obstructive pulmonary disease; CRSsNP: chronic sinusitis without nasal polyposis;

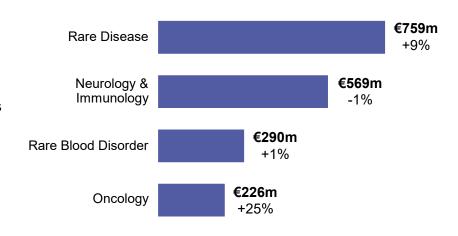
AFRS: allergic fungal rhinosinusitis; (1) Liberty AD OLE; (2) All ages (excl, <6y), U.S. patients on treatment data through May 2021; (3) Pivotal clinical studies (DRI, QUEST, VENTURE, TRAVERSE); (4) IQVIA Patients on Treatment data adjusted for patients (8) U.S. biologics eligible patient population in AD, all channels in asthma indication through May 2021; (5) IQVIA Source of Business Sanofi adjusted for all channels in asthma

indication, Q2'21; (6) Investigational programs not yet reviewed by any regulatory authority: (7) Years in chart represent first submission in U.S. and numbers represent biologics eligible asthma and CRSwNP (9) Excluding Type 2 COPD

Emerging Oncology drove Specialty Care growth in Q2

- Rare Disease franchises grew across geographies
 - Pompe +15%, Fabry +9%, and Gaucher +2% which reflects phasing in some RoW countries
 - Avalglucosidase alfa FDA PDUFA August 18, 2021
- Neurology & Immunology up 14% ex-U.S.
 - U.S. Aubagio[®] -7% due to expected competitive pressures
- RBD franchise up 17% ex Sobi⁽¹⁾ supply sales
 - Alprolix[®] and Cablivi[®] contributed to U.S. growth, +12%
- Oncology new product portfolio rapid growth
 - Sarclisa® and Libtayo® up 300%, offsetting impact from Jevtana® generics in EU

Q2 2021 sales and growth by franchise

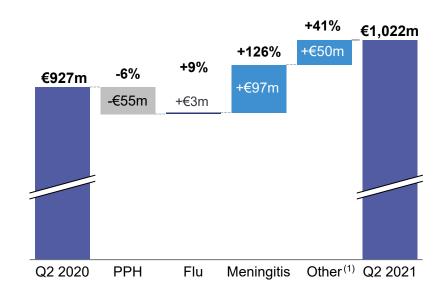




Vaccines – strong growth in Q2 driven by U.S. performance

- Vaccines Q2 2021 sales up 16%
- Strong growth in U.S. reflected prior year's low base for comparison due to confinements
 - Meningitis up 198%, back to pre-pandemic trajectory
 - PPH and Boosters up 48% and 69%, respectively
 - Successful launch of Vaxelis[™] and MenQuadfi[®]
- PPH sales in Europe and Rest of World down 14%
 - COVID vaccination campaigns prioritized
 - Lower birth rates

Vaccines growth by key franchise



Vaxelis[™] – first and only U.S. pediatric six-in-one vaccine

At least 2 fewer shots in infant vaccination series compared to pentavalent vaccines

New option after Vaxelis[™] launch Available pentavalent options before Vaxelis™ launch 2 months 2 months 5-in-1 Vaxelis alternative 4 months 3 shots 4 months shots Hib HepB 6 months 6 months 18 18 Pentacel DTaP + Hib months months Booster Booster Quadracel® Quadracel® 4-in-1 alternative vaccine 4 year 4 vears vaccine

Protects infants and children against six infectious agents (DTaP, Hib, IPV, HepB)



Creation of a first-of-its kind mRNA Center of Excellence



Vision & Ambition

- Become a leading mRNA vaccine player within 5 years
- New technology added to Sanofi Vaccine's toolbox
- Focus on innovative mRNA vaccines beyond pandemic use



Accelerating execution

- Significant investment funded through resource reallocation
- 400 dedicated employees in the U.S. (Cambridge) and France (Lyon)
- Bringing together **end-to-end capabilities** in an integrated organization



Focusing on next generation mRNA vaccines

- Vaccines R&D fully leveraging digitalized environment
- World-class industrial manufacturing capabilities
- Developing both unmodified and modified mRNA

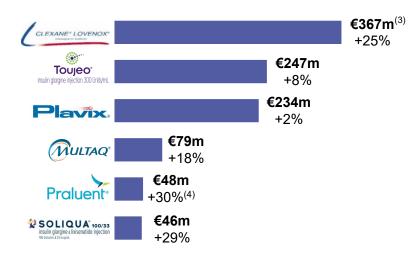
Ambition to deliver a minimum of six clinical candidates by 2025



General Medicines delivered on strategic priorities in Q2

- Strong performance of core assets, €1.4bn +12%⁽¹⁾
 - Growth driven by demand for the six key brands and recovery of transplant portfolio⁽²⁾
- Positive Soliqua® SoliMix data presented at ADA
- Non-core assets of €1.9bn broadly stable
 - Portfolio streamlining impacted sales growth by 1.6 ppts
- Eloxatin® bidding win in China VBP Wave 5
 - Implementation expected in Q4 2021
- Simplification through focused geographic footprint
 - Trimmed infrastructure in European countries⁽⁵⁾

Strong growth of 6 core assets in Q2 2021



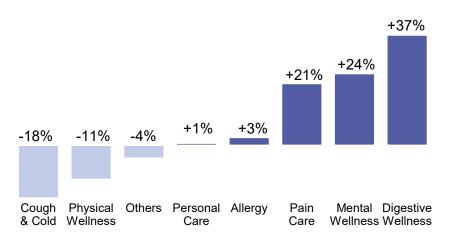
All growth at CER; ADA: American Diabetes Association; ppts: percentage points; VBP: volume based procurement

- (1) Excluding U.S. Praluent Q2 2020 sales, the growth of the core brands was 15%
- (2) Transplant portfolio includes Mozobil® and Thymoglobulin® which grew 45% globally
- (3) Excluding auto generics
- (4) Growth rate calculation excludes U.S. Praluent sales in Q2 2020
- (5) Subject to completion of social process

Consumer Healthcare returned to growth

- CHC Q2 sales of €1.1bn with growth across all key geographies
- Digestive Wellness: a key growth contributor in Q2
 - Enterogermina®, Buscopan®, Dulcolax® strong growth
 - Liver care driven by Essentiale® +22%
- Acceleration of e-commerce
- Further simplification of our portfolio
 - Announced divestments in Europe and Latin America
- · Progressing on 'carve-in' project as planned

CHC Q2 2021 sales up 12%

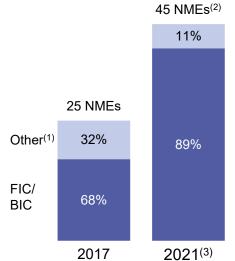


On track to create a 'Fast Moving Consumer Health' business



Prioritization and execution driving pipeline transformation

Building a sustainable first-in-class / best-in-class pipeline



Potential FIC / BIC assets include:

- Amcenestrant in breast cancer
- Tolebrutinib in multiple sclerosis
- Efanesoctocog alfa in hemophilia A
- SAR'245 in solid tumors
- SAR'229 (anti-Ox40L) / SAR'656 (IRAK4 degrader) / SAR'727 (BTKi topical) in atopic dermatitis

Addition of cutting-edge technologies













FIC/BIC: first-in-class / best-in-class; SAR'656 development in collaboration with Kymera (KT474); Efanesoctocog development in collaboration with Sobi; Pipeline programs represent assets under investigation and are not approved by regulators for the uses being investigated.

- (1) Other: still in early stage with data developing or undifferentiated molecules
- (2) New Molecular Entities (NMEs) include life cycle management of approved medicines with additional indications in development in specialty care
- (3) As of June 30, 2021

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Amcenestrant – Potential best-in-class endocrine backbone in ER+ breast cancer across treatment lines

Amcenestrant molecular structure

Degrader chain

N

F

CI

CI

Scaffold

- Full receptor occupancy at doses as low as 150mg QD⁽²⁾
- No clinically significant bradycardia, QTc prolongation, or ocular toxicity

2/3L monotherapy

Efficacy (Phase 1)(3):

- · CBR of 36% in all patients
- CBR of 64% in patients without prior SERD, CDK4/6 or mTORi

Safety:

TRAEs all grade 1-2



Submission 2022⁽¹⁾

1L combination with palbociclib

Efficacy (Phase 1)⁽⁴⁾:

- ORR of 34%
- CBR of 74%

Safety:

 Amcenestrant TRAEs similar to monotherapy



Submission 2024⁽¹⁾

Adjuvant









Submission 2026⁽¹⁾

CBR: clinical benefit rate; ORR: objective response rate; TRAEs: treatment related adverse events; SERD: selective estrogen receptor degrader; ER+: estrogen receptor positive; CDK: cyclin-dependent kinases; QD: once daily

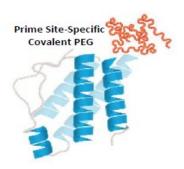
- (1) Expected submission
- (2) ASCO 2019 (3) ASCO 2020
- (4) ASCO 2021



Amcenestrant is an asset under investigation, not approved by regulators. AMEERA-6 is in collaboration with BIG. EORTC and Alliance

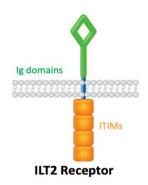
Q2 advancements in emerging oncology pipeline

SAR'245: Potential best-in-class IL-2



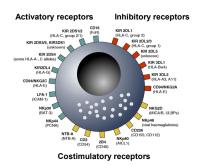
- First patient in skin⁽¹⁾ and lung⁽²⁾ trials expected shortly
- Head and neck plus 2 additional basket trials to start by year end

SAR'881⁽³⁾: Potential first-in-class ILT-2 antagonist



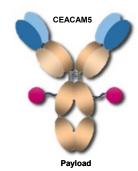
- Next generation checkpoint inhibitor targeting ILT2 receptor
- First patient dosed in Phase 1 clinical trial

SAR'419: Proprietary off-the-shelf NK cells



- SAR'419, Kiadis proprietary off-the-shelf NK-cell-based immunotherapy
- Added to Phase 1

Tusamitamab ravtansine: anti-CEACAM5 ADC



- Internally developed ADC;
 Phase 3 in metastatic Non-squamous NSCLC on-going
- Phase 2 basket trial in pancreatic and breast cancer started



Key Pharma R&D milestones expected in H2 2021

CANDIDATE	INVESTIGATIONAL INDICATION(S)	MILESTONES
Dupixent ^{®(1)}	Prurigo nodularis Eosinophilic esophagitis Atopic Dermatitis	 Phase 3 data Phase 3 Part B data Phase 3 data in <6yo
Amcenestrant	ER+ breast cancer	 Phase 2 pivotal data in 2L/3L monotherapy (AMEERA-3) Phase 3 trial in adjuvant patients to start (AMEERA-6)
Sarclisa [®]	Multiple myeloma	 Phase 1/2 SC formulation Phase 3 MRD induction data (GMMG) Phase 3 data in 1L transplant ineligible (IMROZ)
Libtayo ^{®(1)}	1L Non-small-cell lung cancer	Phase 3 data in combination with chemotherapy
Rilzabrutinib	Pemphigus Vulgaris Type 2 Inflammatory diseases	 Phase 3 data Phase 2 trials to start in asthma, CSU, and atopic dermatitis
SAR'136 ⁽²⁾	Sickle cell disease	Phase 1/2 interim data
SAR'229 ⁽³⁾	Atopic dermatitis	Phase 2b trial to start; Phase 2 data presentation
SAR'245	Multiple tumor types	 Phase 2 programs in thoracic, skin, head and neck cancers to start Phase 2 additional basket trials to start
Tolebrutinib	New indication	Phase 2 trial start

>5 NMEs including nanobodies to enter development



EPS up 16% driven by sales growth

€m	Q2 2021	Q2 2020	% Change (CER)
Net Sales	8,744	8,207	+12.4%
Other revenues	301	231	+43.3%
Gross Profit	6,188	5,778	+13.5%
Gross margin %	70.8%	70.4%	
R&D	(1,397)	(1,352)	+7.0%
SG&A	(2,336)	(2,265)	+8.1%
Operating Expenses	(3,733)	(3,617)	+7.7%
Other current operating income & expenses	(199)	(8)	
Business Operating Income	2,265	2,146	+13.8%
Business operating margin	25.9%	26.1%	
Effective tax rate	21.0%	22.0%	
Total Business Net Income	1,731	1,601	+16.8%
Average number of shares	1,251.3	1,252.2	
Business EPS	1.38	1.28	+16.4%

Q2 earnings drivers

- Accelerated top-line growth
- Gross Margin ratio expansion (70bps at CER) due to improved product mix and savings partially offset by unfavorable fx rates and short shelf-life product write-offs
- R&D spend increased behind priority assets and recent acquisitions, partly off-set by efficiencies
- Higher SG&A reflecting commercial investments behind Specialty Care growth drivers compared to lower base of prior year
- Other Operating Income included capital gains from divestments⁽¹⁾



On track to achieve 2022 BOI margin target of 30%

€m	H1 2021	H1 2020	% Change (CER)
Net Sales	17,335	17,180	+7.2%
Other revenues	596	574	+13.6%
Gross Profit	12,390	12,247	+7.7%
Gross margin %	71.5%	71.3%	
R&D	(2,663)	(2,692)	+2.7%
SG&A	(4,530)	(4,607)	+3.6%
Operating Expenses	(7,193)	(7,299)	+3.3%
Other current operating income & expenses	(300)	(255)	+35.3%
Business Operating Income	4,903	4,683	+13.6%
Business operating margin	28.3%	27.3%	
Effective tax rate	21.0%	22.0%	
Total Business Net Income	3,748	3,521	+15.6%
Average number of shares	1,250.3	1,251.7	
Business EPS	3.00	2.81	+16.0%

H1 earnings drivers

- Top-line growth of 7% driven by Dupixent[®],
 Vaccines and GenMed core brands⁽¹⁾
- Higher gross margin (40bps at CER) due to improved product mix and industrial efficiencies
- Operating expense increase driven by investment in growth drivers
- OOI&E includes one-offs received in both periods⁽²⁾
 offsetting growing mAbs profit share payments

Dupixent® expected to be accretive to BOI margin in 2022

All growth at CER unless footnoted; bps: basis points; mAbs: monoclonal antibodies; BOI: Business Operating Income. BOI is a non-GAAP financial indicator



H1 2020 included a gain of €157m related to a revaluation of retained Regeneron shares and H1 2021 included a €119m payment from Daiichi Sankyo related to the termination of a vaccines collaboration in Japan.



All €450m of incremental savings in H1 reinvested

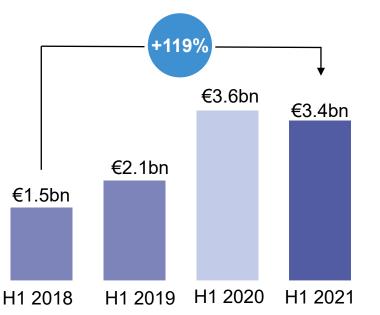


€2.1bn of cumulative savings identified to date; on track to achieve target of €2.5bn by 2022⁽¹⁾



Strong trend of free cash flow improvement continues

Free Cash Flow⁽¹⁾ evolution



Free Cash Flow⁽¹⁾ growth drivers

- Business performance
- Smart spending initiatives
- Asset disposals driving H1 2020
 - €682m⁽²⁾ in H1 20 vs. €247m in H1 2021
- Cash outflow of €558m⁽³⁾ due to M&A and BD in H1 2021

On track to improve FCF by 50%⁽⁴⁾ by 2022

- (1) Free Cash Flow (FCF) definition in Financial appendices
- (2) Including Seprafilm, JV with MSD and a portfolio of EP products sold for €313m, €167m and €105m before tax respectively; includes Daiichi Sankyo settlement in 2021
- 3) Biond, Kiadis, Tidal Therapeutics
- (4) From 2018 base, exchange rate at the time of December 2019 Capital Markets Day



Expected business dynamics in H2 2021

Pharmaceuticals GenMed core assets to grow overall with Lovenox® growth slowing; additional divestitures; China VBP Wave 5 implementation and uncertainties around mechanism for insulin class inclusion Record flu sales, further recovery of meningitis franchise, continued weakness of travel vaccines, and lower PPH sales following Vaxelis™ launch and lower birth rates Further progress on business simplification, continued expansion in e-commerce, and cough & cold franchise to at least stabilize Continued improvement in gross margin;

Specialty Care expected to grow with Dupixent® the key driver;

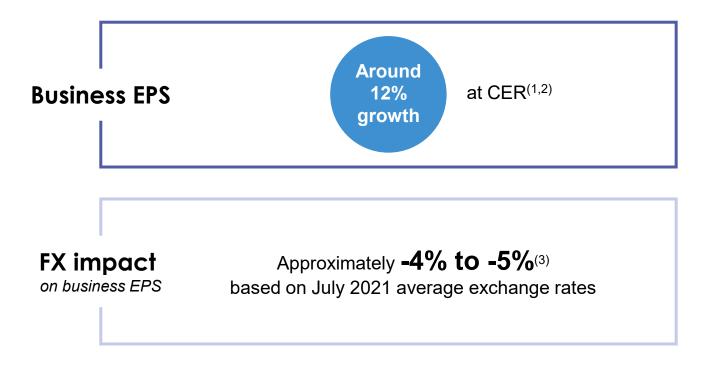
Save the Date: Vaccines Investor Event in Q4 2021

Increase in R&D spend compared to 2020



Non-sales line items

FY 2021 business EPS guidance raised



⁽²⁾ Base for FY 2020 Business EPS growth is €5.86 and excluding the effect of the equity method of accounting for the Regeneron investment in the share of profit/loss of associates and joint ventures line



⁽¹⁾ Compared to FY2020 and barring major unforeseen adverse events

Q&A session



Paul Hudson CEO



Olivier Charmeil General Medicines



Julie van Ongevalle Consumer Healthcare



Bill Sibold Specialty Care



Jean-Baptiste de Chatillon CFO



Karen Linehan Legal Affairs and General Counsel



John Reed R&D



Thomas Triomphe Vaccines





Financial appendices

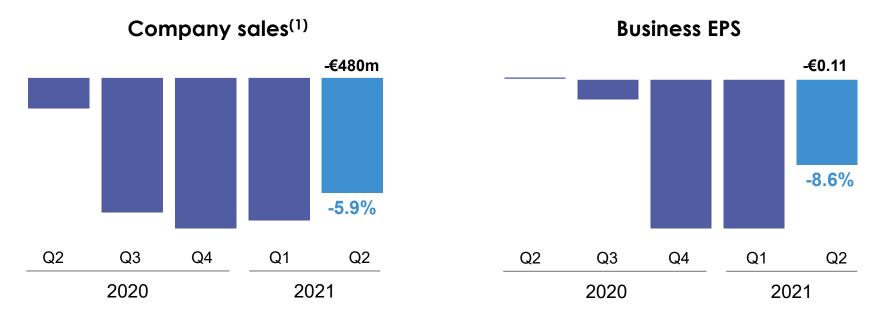
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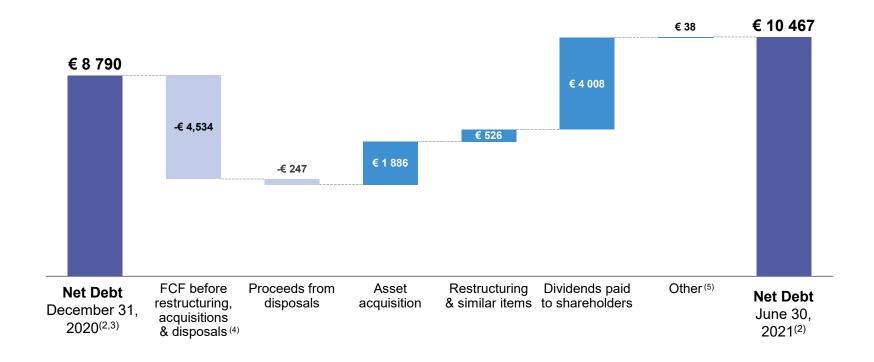
Q2 sales and EPS impacted by continued weakening of U.S. dollar and Emerging Markets currencies

Currency impact





Net debt evolution in H1 2021⁽¹⁾





⁽²⁾ Including derivatives used to manage net debt: €193m at December 31, 2020 and €28m at June 30, 2021

(4) Free Cash Flow (FCF) includes restructuring costs cash-out, investments and divestments

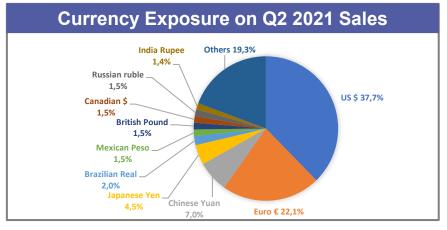
⁽⁵⁾ Including €140m use of funds from acquisition of treasury shares and €23m of proceeds from issuance of Sanofi shares



⁽³⁾ Effective January 1, 2019, net debt does not include lease liabilities following the first-time application of IFRS 16

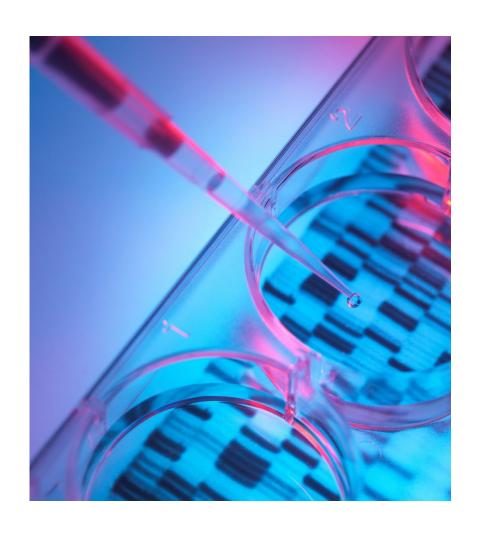
2021 currency sensitivity and Q2 2021 currency exposure

2021 Business EPS Currency Sensitivity			
Currency	Variation	Business EPS Sensitivity	
U.S. Dollar	+ 0.05 USD/EUR	- EUR 0.13	
Japanese Yen	+ 5 JPY/EUR	- EUR 0.02	
Chinese Yuan	+ 0.2 CNY/EUR	- EUR 0.02	
Brazilian Real	+ 0.4 BRL/EUR	- EUR 0.01	
Russian Ruble	+ 10 RUB/EUR	- EUR 0.02	



Currency Average Rates			
	Q2 2020	Q2 2021	% change
EUR/USD	1.10	1.21	+9.5%
EUR/JPY	118.31	131.91	+11.5%
EUR/CNY	7.81	7.79	-0.3%
EUR/BRL	5.92	6.39	+7.8%
EUR/RUB	79.66	89.49	+12.3%





R&D appendices

Q2 2021 results

July 29, 2021



Expected 2021 R&D key timelines

	Product	Milestones	Comment	Achieved / Missed ⁽¹⁾
	avalglucosidase alfa	U.S. regulatory decision, PDUFA May 18 (Pompe disease)	Fast track designation, BTD, Priority review	× H2 2021 ⁽³⁾
	Libtayo ^{®(2)}	U.S. regulatory decision, PDUFA Feb 28 (1L NSCLC PD-L1 ≥50%)	Priority review	✓
	Libtayo ^{®(2)}	U.S. regulatory decision, PDUFA March 3 (advanced BCC)	Priority review	✓
11 2021	Sarclisa [®]	U.S. regulatory decision PDUFA July 18 (RMM-IKEMA)		✓
11 2021	amcenestrant	Pivotal data from AMEERA-3 in 2/3L mBC	Fast track designation	× H2 2021 ⁽⁴⁾
	Libtayo ^{®(2)}	Pivotal data in 1L NSCLC combo with chemotherapy		× H2 2021 ⁽⁴⁾
	Libtayo ^{®(2)}	Pivotal data in 2L Cervical Cancer		✓
	amcenestrant	Phase 3 decision for early breast cancer	Fast track designation	✓
	avalglucosidase alfa	EU regulatory decision (Pompe disease)		
	Dupixent®(2)	U.S. regulatory decision (Asthma 6 to 11-year)		
	Sarclisa [®]	EU regulatory decision (Relapsed Multiple Myeloma - IKEMA)		✓
2 2021	Dupixent ^{®(2)}	Pivotal trial read-out (Chronic Spontaneous Urticaria – CSU)		✓
	Dupixent ^{®(2)}	Pivotal trial read-out (Prurigo Nodularis – PN)		
	rilzabrutinib	Pivotal trial read-out (Pemphigus)	U.S. and EU orphan designation	
	Sarclisa [®]	Pivotal trial read-out (1L TiMM– IMROZ)		
2021		munology, Oncology, and RBD in 2021 to the clinical pipeline		



- (2) Developed in collaboration with Regeneron
- (3) FDA PDUFA 3-month extension to August 18, 2021
- (4) Event driven trial



R&D Pipeline – Phase III & Registration

-	Phase III	•				
Name	Description	Indication		Name	De	
amcenestrant	SERD + palbociclib	1L Metastatic breast cancer		Dupixent®(1)	Anti-IL4/IL13 n	
Libtayo ^{®(1)}	Anti-PD-1 mAb + chemotherapy	1L NSCLC		avalglucosidase alfa	Enzyme replace	
Libtayo ^{®(1)}	Anti-PD-1 mAb	2L Cervical Cancer		sutimlimab	Anti-compleme	
Libtayo ^{®(1)}	Anti-PD-1 mAb	Adjuvant CSCC				
Sarclisa [®]	Anti-CD38 mAb	1L Newly Diag. MM Ti (IMROZ)		Oncology	Rare B	
Sarclisa [®]	Anti-CD38 mAb	1L Newly Diag. MM Te (GMMG)		Immuno-inflammation	Neurol	
Sarclisa®	Anti-CD38 mAb	Smoldering MM (ITHACA)		Rare Diseases	Vaccin	
tusamitamab ravtansine	Anti-CEACAM5 ADC	NSCLC 2/3L				
Dupixent ^{®(1)}	Anti-IL4/IL13 mAb	Atopic Dermatitis 6 months - 5 years old		.C: non small cell lung cancer; C Multiple Myeloma; ADC: Antibod		
Dupixent ^{®(1)}	Anti-IL4/IL13 mAb	Prurigo Nodularis		ase; ERT: enzyme replacement		
Dupixent ^{®(1)}	Anti-IL4/IL13 mAb	Eosinophilic Esophagitis	(1)	Developed in collaboration with	Regeneron	
Dupixent ^{®(1)}	Anti-IL4/IL13 mAb	Bullous Pemphigoid	(2)	Developed in collaboration with	th Sobi	
Dupixent ^{®(1)}	Anti-IL4/IL13 mAb	Chronic Spontaneous Urticaria		Recombinant Coagulation Fact Developed in collaboration with		
Dupixent ^{®(1)}	Anti-IL4/IL13 mAb	Chronic Obstructive Pulmonary Disease	(5)	Developed in collaboration with		
Dupixent ^{®(1)}	Anti-IL4/IL13 mAb	Chronic Inducible Cold Urticaria		(BARDA)		
Dupixent ^{®(1)}	Anti-IL4/IL13 mAb	Chronic Rhinosinusitis without Nasal Polyps	As of	June 30, 2021		
Dupixent ^{®(1)}	Anti-IL4/IL13 mAb	Allergic Fungal Rhinosinusitis				
rilzabrutinib	BTK inhibitor	Pemphigus Vulgaris				
itepekimab ⁽¹⁾	Anti-IL33 mAb	Chronic Obstructive Pulmonary Disease				
venglustat	Oral GCS inhibitor	GM2 Gangliosidosis				
Cerdelga [®]	Oral GCS inhibitor	Gaucher T1, ERT switch, Pediatric				
fitusiran	RNAi targeting anti-thrombin	Hemophilia A and B				
fitusiran	RNAi targeting anti-thrombin	Hemophilia A and B pediatric				
rilzabrutinib	BTK inhibitor	Immune Thrombocytopenia				
efanesoctocog alfa (BIVV001)(2)	rFVIIIFc – vWF – XTEN ⁽³⁾	Hemophilia A				
tolebrutinib	BTK inhibitor	Relapsing Multiple Sclerosis (RMS)				
tolebrutinib	BTK inhibitor	Primary Progressive MS (PPMS)				
tolebrutinib	BTK inhibitor	Secondary Progressive MS (SPMS)				
nirsevimab ⁽⁴⁾	Monoclonal Antibody	Respiratory Syncytial Virus				
SP0253 ⁽⁵⁾	Recombinant baculovirus vaccine	COVID-19				
MenQuadfi™	Meningococcal (A,C,Y,W) conjugate vaccine	Meningitis 6w+ (US / EU)				
VerorabVax® (VRVg)	Purified vero rabies vaccine	Rabies				



Name	Description	Indication
Dupixent ^{®(1)}	Anti-IL4/IL13 mAb	Asthma 6-11 years old
avalglucosidase alfa	Enzyme replacement therapy	Pompe Disease
sutimlimab	Anti-complement C1s mAb	Cold Agglutinin Disease
Oncology Immuno-inflammation Rare Diseases	Rare Blood Disorders Neurology Vaccines	

squamous cell carcinoma; Ti: Transplant ineligible; Te: Transplant eligible; BTKi: Bruton's Tyrosine Kinase inhibitor; GCS: Glucosylceramide elective estrogen receptor degrader

- llebrand Factor XTEN Fusion protein
- iding from Biomedical Advanced Research and Development Authority



R&D Pipeline – Phase I & II

Name	Phase I Description	Indication
 SAR439459	Anti-TGFb mAb	Advanced Solid Tumors
SAR441000 ⁽⁴⁾	Cytokine mRNA	Solid tumors
SAR442085	Anti CD38 mAb Fc engineered	Multiple Myeloma
SAR442257	Anti-CD38xCD28xCD3 trispecific mAb	MM / N-H Lymphoma
SAR442720 ⁽³⁾	SHP2 inhibitor mono, combo	Solid tumors
SAR444245 ⁽¹⁷⁾	Non-alpha IL-2 mono, combo (PD-1, EGFR)	Solid tumors
SAR444881 ⁽¹⁸⁾	Anti-ILT2	Solid tumors
SAR445419 ⁽²⁰⁾	NK-cell-based immunotherapy	Acute Myeloid Leukemia
SAR444727	BTK inhibitor (topical)	Immune mediated diseases
SAR441566	Oral TNF inhibitor	Inflammatory indications
SAR444656 ⁽¹⁴⁾	IRAK4 degrader	Atopic dermatitis
SAR442501	FGFR3 antibody	Achondroplasia
ST400 ⁽¹⁶⁾	Ex Vivo ZFN Gene-Edited Cell Therapy	Beta thalassemia
SAR445136(5,16)	Ex Vivo ZFN Gene-Edited Cell Therapy	Sickle Cell Disease
SAR445088 ⁽¹³⁾	Complement C1s inhibitor	Cold Agglutinin Disease
SAR443820 ^(6,7)	RIPK1 ⁽⁹⁾ inhibitor	Amyotropic Lateral Sclerosis
SP0148 ⁽¹⁰⁾	HSV-2 therapeutic vaccine	Herpes Simplex Virus (HSV) Type 2
SP0273 ⁽¹⁵⁾	mRNA vaccine	Influenza vaccine

Oncology Immuno-inflammation Rare Diseases

Rare Blood Disorders Neurology Vaccines

R Registrational Study (other than Phase 3)

MM: Multiple Myeloma; FGFR3: Fibroblast Growth Factor Receptor 3; NSCLC; Non-Small Cell Lung; ALL; Acute Lymphoblastic Leukemia; ASMD; Acid sphingomyelinase deficiency; CIDP: Chronic inflammatory demyelinating polyneuropathy; SERD: selective estrogen receptor degrader; GCS: Glucosylceramide Synthase

- (1) Formerly known as KY1044
- Developed in collaboration with Immunext
- Medicines Developed in collaboration with BioNTech
- Formerly known as BIVV003
- Developed in collaboration with Denali
- Also known as DNL788
- Also known as DNL758

- (9) Receptor-Interacting serine/threonine-Protein (15) Developed in collaboration with Translate Bi
- Developed in collaboration with Revolution (10) Developed in collaboration with Immune Design/Merck
 - (11) Developed in collaboration with SK
 - (12) Developed in collaboration with Regeneron (20) Formerly known as KDS1001
 - (13) Formerly known as BIVV020
 - (14) Developed in collaboration with Kymera (KT474)

- (16) Developed in collaboration with Sangamo (17) Formerly known as THOR707
- (18) Developed in collaboration with Biond (19) Formerly known as KY1005

Phase II

	riidse ii			
	Name	Description	Indication	
R	amcenestrant	SERD	Metastatic Breast Cancer 2/3L	
	amcenestrant	SERD	Early Breast Cancer	
	SAR445256 ⁽¹⁾	Anti-ICOS	Solid tumors	
	tusamitamab ravtansine	Anti-CEACAM5 ADC + ramucirumab	2/3L NSCLC	
	tusamitamab ravtansine	Anti-CEACAM5 ADC	Exploratory Solid tumors	
	tusamitamab ravtansine	Anti-CEACAM5 ADC + pembrolizumab	1L NSCLC	
	Sarclisa [®]	Anti-CD38 mAb+ combinations	Relapsed, Refractory Multiple Myeloma	
	Sarclisa [®]	Anti-CD38 mAb + atezolizumab	Metastatic Colorectal Cancer 1L	
R R	Sarclisa [®]	Anti-CD38 mAb	1-2L AML / ALL pediatrics	
R	Sarclisa [®]	Anti-CD38 mAb	Patients awaiting kidney transplantation	
	SAR443122 ^(6,8)	RIPK1 ⁽⁹⁾ inhibitor	Cutaneous Lupus Erythematosus	
	SAR445229 ⁽¹⁹⁾	Anti-Ox40L	Atopic Dermatitis	
	Dupixent ^{® (12)}	Anti-IL4/IL13 mAb	Peanut allergy	
R R	Kevzara ^{®(12)}	Anti-IL6 mAb	Polyarticular Juvenile Idiopathic Arthritis	
R	Kevzara ^{®(12)}	Anti-IL6 mAb	Systemic Juvenile Arthritis	
	rilzabrutinib	BTK inhibitor	lgG4-related disease	
	SAR441344 ⁽²⁾	Anti-CD40L mAb	Sjogren's Syndrome	
R	olipudase alfa	rhASM	ASMD ad+ped	
	SAR339375	miRNA-21	Alport Syndrome	
	venglustat	Oral GCS inhibitor	Fabry Disease	
R	venglustat	Oral GCS inhibitor	Gaucher Type 3	
	SAR445088 ⁽¹³⁾	Complement C1s inhibitor	Immune Thrombocytopenia	
	SAR445088 ⁽¹³⁾	Complement C1s inhibitor	CIDP	
	SAR441344 ⁽²⁾	Anti-CD40L mAb	Multiple Sclerosis	
	SP0218	Vero cell	Yellow fever vaccine	
	SP0202 ⁽¹¹⁾	Next Generation Conjugate Vaccine	Pneumococcal	
Bio	Fluzone® HD (SP0178)	Inactivated influenza Vaccine (IIV)	Pediatric Flu	
	SP0125	Vaccine	Respiratory syncytial virus (infants)	
	SP0254 ⁽¹⁵⁾	mRNA vaccine	COVID-19	
	SP0230	Multicomponent vaccine	Meningitis B	

As of June 30, 2021



Expected submission timelines⁽¹⁾

nirsevimab(7) Respiratory syncytial virus mRNA vaccine(5) COVID-19 rilzabrutinib fitusiran Pemphigus Vulgaris Hemophilia A/B SP0253(4) olipudase alfa tusamitamab ravtansine efanesoctocog alfa(6) tolebrutinib itepekimab(3) ASMD ad+ped RMS, PPMS, and SPMS COVID-19 BIVV001 Hemophilia A **2021**⁽²⁾ 2022(2) **2023**⁽²⁾ 2024 and beyond⁽²⁾ Sarclisa® Dupixent®(3) Dupixent®(3) Dupixent®(3) venglustat venglustat VerorabVax® (VRVg) Prurigo nodularis AD 6 months - 5 years old Gaucher Type 3 Fabry Disease Purified vero rabies vaccine Dupixent®(3) Cerdelga® Libtavo®(3) + chemo Dupixent®(3) rilzabrutinib MenQuadfi™ venglustat Gaucher T1. ERT(8) switch. Chronic spontaneous Bullous pemphigoid ITP GM2 gangliosidosis U.S. & EU: 6w+ Pediatric Kevzara®(3) Dupixent®(3) Dupixent®(3) fitusiran Libtayo®(3) Polyarticular juvenile Eosinophilic esophagitis Hemophilia A/B pediatric idiopathic arthritis Nasal Polyps Dupixent®(3) Dupixent®(3) Sarclisa® Allergic Fungal Rhinosinusitis 1-2L AML / ALL ped. Urticaria Sarclisa® Kevzara®(3) Immuno-inflammation Rare Blood Disorders Newly Diagnosed MM Te Systemic Juvenile Arthritis Oncology Neurology Rare Diseases Vaccines

As of June 30, 2021, barring unforeseen events

- (1) Excluding Phase 1 (without POC)
- (2) Projects within a specified year are not arranged by submission timing
- (3) Developed in collaboration with Regeneron

Additional Indications

- (4) Developed in collaboration with GSK and with funding from Biomedical Advanced Research and Development Authority (BARDA)
- 5) Developed in collaboration with Translate Bio
- (6) Developed in collaboration with Sobi

- (7) Developed in collaboration with AstraZeneca
- Enzyme replacement therapy

RMS: Relapsing multiple sclerosis, PP: Primary progressive; SP: Secondary progressive; TP: Immune Thrombocytopenia; MM: Multiple myeloma; CSCC: cutaneous squamous cell carcinoma; AML: acute myeloid leukemia; ALL: acute lymphoblastic leukemia; COPD: chronic obstructive pulmonary disease; Te: transplant eligible; Ti transplant ineligible; ped: pediatric; NSCLC: non-small cell lung cancer, mBC: metastatic breast cancer, ASMD: acid sphingomyelinase deficiency; ad+ped: adults and pediatric



Update on COVID-19 vaccine development programs

Platform 2021 Expected timeline Mav Phase 2 interim data Phase 3 results **February** Recombinant Phase 2 start and submission **Protein** June approach(1) Phase 3 start Phase 1/2 March **mRNA** interim data Phase 1/2 start approach(2)

Progressing on preclinical studies and manufacturing activities on variants

